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510 K Summary of Safety and Effectiveness

according to 21 CFR 807.92

MAY 19 2006

A1 Address

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Contact Name: Mr. Markus Buetler
Tel: 001 41 41 766 4252
Date: 02.th May 2006

A2 Device Name

1. Trade Name: Argus LCM (Basic / Plus)
2. Common Name: Monitoring System

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:

ARGUS PB-1000 System	K012226
Cardiovit AT-102	K031557

A4 Intended Use

The Monitoring System ARGUS LCM is for the monitoring of vital parameters such as:

- ECG: Heartrate, Respiration Rate
- Invasive Blood Pressure: systolic, diastolic and mean pressure
- Temperature: temperature
- Non Invasive Blood Pressure: systolic, diastolic and mean pressure
- CO_2, etCO_2 and CO_2ins and respiration rate.
- SpO_2: SpO_2 and pulse rate

There is alarm handling for all parameters except temperature.
The ARGUS LCM is powered via the normal mains connection 230V/110V, and using an internal battery and an external power input.
The system is inteded for use in the Intensive Care Unit, in the Recovery Room, in the Operation Room and during hospital internal transport.

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A5 Table of Comparison (1)

		Argus PB-1000 System (K012226)		ARGUS LCM
Dimensions:		210x115x45mm		290x275x180mm [1)]
Weight:		980 g		4.6 kg / 9.2lbs [2)]
Environmental Conditions:				
Operating temperature		+10° - 40° C		same
Storage temperature		-10° - +50° C		same
Relative humidity		25% - 95% (non condensing)		same

Discussion of Differences:
None of the above differences (1 or 2) can be considered as safety relevant differences.
We consider the submitted device to be as safe and effective as the Predicate ARGUS PB-1000 (K 012226) device.

Table of Comparison (2)

LCM Plus	LCM Basic	Module	Description	Reference	Standards
X	X	System	Schiller AT-102	K031557, Schiller AT-102	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-4
X		ECG	Schiller AT-102	K031557, Schiller AT-102	IEC 60601-1 IEC 60601-2-2
	X	ECG 3p	New Schiller ECG Hardware amplifier	-	IEC 60601-1 IEC 60601-2-2
			Amplifier Firmware	K031557, Schiller AT-102	IEC 60601-1 IEC 60601-2-2
			Filtering	K031557, Schiller AT-102	IEC 60601-1 IEC 60601-2-2
			Algorithm	K031557, Schiller AT-102	IEC 60601-1 IEC 60601-2-2
X	X	SPO2	Masimo OEM SpO2 Module MS-7	K990966, Masimo SET 2000	Verification an Test Documen
X	X	SPO2	Nellcor OEM SpO2 Module MP-100	K021090, Nellcor N-550 Pulse Oximeter	Verification an Test Documen
X	X	NIBP	Schiller NIBP Module ARGUS PB-1000	K012216, Schiller ARGUS PB-1000 System	IEC 60601-2-3
X	X	Temp.	Schiller Temperature Module ARGSU PB-1000	K012216, Schiller ARGUS PB-1000 System	EN 12470-4
X	X	CO2	Welch Allyn OEM CO2 Module LC101	K022084, Welch Allyn Atlas Monitor	Specifications. Declaration
X	X	IBP	Schiller IBP Module ARGUS PB-1000	K012216, Schiller ARGUS PB-1000 System	IEC 60601-2-3

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B1 Non-Clinical Tests

1. Electrical Safety and Reliability:

The device has been tested to be in accordance with the following standards:
EN 60601-1:1990: *Safety of Medical Electrical Equipment part 1, General requirements.*
IEC60601-1-2: *Electromagnetic Compatibility Test, Electrostatic Discharge, Radio Frequency Electromagnetic Field, Fast Transients.*
IEC60601-2-27:1996 *Particular Requirements for the safety of electrocardiographic monitoring equipment.*

IEC60601-2-30:1995 *Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.*
IEC60601-2-34:1995 *Particular requirements for the safety of the blood pressure monitoring equipment.*
IEC60601-2-49:2001 *Particular Requirements for the safety of multifunction patient monitoring equipment*
EN865:1997 *Pulse Oximeters-Particular Requirements*

All tests are passed.

4) Data related to software quality

SCHILLER has reviewed its software development process following the guideline " reviewer guidance for computer controlled medical devices undergoing 510 (k) review". Device software requirements, software structure chart, software development, software revision/ modification, software identification, software verification, validation and testing are described in the data attached.

B2 Clinical Tests

n.a.

B3 Summary of Performance Testing:

The Argus LCM Monitoring and associated accessories have been tested and found to comply with recognized national and international performance, safety and electromagnetic compatibility standards for medical devices and product specifications listed in the Argus LCM labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of SCHILLER AG, product development procedures. SCHILLER AG Quality System conforms to 21 CFR 820 and is Certified to ISO 9001:2000 and ISO 13485:2003

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Conclusion

As stated above, SCHILLER AG conclusion is that the Argus LCM Monitoring is safe, effective, comply with the appropriate medical device standards and equivalent to the Argus PB-1000 System (K012226) and Cardiovit AT-102 (K031557) currently on the market.

Baar (Switzerland) 02th May 2006

Markus Buetler
SCHILLER AG
Quality Assurance and Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

Mr. Markus Buetler
Quality and Regulatory Department
Schiller AG
Altgasse 68
Baar, ZG,
Switzerland 6341

Re: K053207
Trade/Device Name: Argus, Model LCM
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: November 11, 2005
Received: November 16, 2005

Dear Mr. Buetler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If know): K053207

Device Name: **Argus LCM**

Indications for Use:

The Monitoring System ARGUS LCM is for the monitoring of vital parameters such as:

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- Invasive Blood Pressure: systolic, diastolic and mean pressure
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10/11/05

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053207